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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/920,263 | 08/01/2001 | Maria Teodorczyk | LFS-121 | 5693 |
| 24353 | 7590 | 01/21/2004 | EXAMINER | |
| BOZICEVIC, FIELD & FRANCIS LLP 200 MIDDLEFIELD RD SUITE 200 MENLO PARK, CA 94025 | | | GITOMER, RALPH J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1651 | |

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/920,263

Applicant(s)

TEODORCYZK ET AL.

Examiner

Ralph Gitomer

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 15-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other: _____

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Applicant's election without traverse of Group I received 12/1/03 is acknowledged. Claims 13 and 14 directed to the dye are free of the art of record.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Tokunaga.

Tokunaga (US 2002/0139692 A1) entitled "Sample Discriminating Method" with a 102(e) date of 11/1999, teaches on page 1 paragraph 3, the control fluid may be a solution of glucose dissolved in pure water or colored with a pigment in accordance with its use. In paragraph 9 the kind of sample can be automatically discriminated so the kind of sample will not be erroneously recognized. See the claims.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-8, 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Ye.

Ye (5,723,284) entitled "Control Solution and Method for Testing The Performance of an Electrochemical Device for Determining the Concentration of an Analyte in Blood" teaches in column 3 last paragraph bridging to column 4, a control solution and a method of testing an amperometric sensing device which automatically allows the sensing device to detect when a control solution rather than blood is being tested. The sensing device has a memory system which automatically excludes the data generated using the control solution from the memory unit for blood data. The control solution provides a dynamic current profile which is distinctly different from that obtained with blood. A number of compositions of glucose control solutions are disclosed.

All the features of the claims are taught by each of the above references for the same function as claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of each of Tokunaga and Ye in view of Rapkin.

See the teachings of the references above.

The claims differ from the above references in that they specify that the control solution does not contain a mediator dissolution slowing component and an oxidizing agent.

Rapkin (WO 95/13536 A1) entitled "Glucose Control Material for Test Strips" teaches on page 7, a glucose control reagent comprising a known amount of glucose, water and clay. It is useful for devices utilizing electrochemical methods for determining glucose.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the presently claimed control solution in the methods and apparatus of Tokunaga and Ye because Tokunaga and Ye describe the control solutions as optionally containing a number of additional components for the same function presently claimed. And Rapkin specifically discloses control solutions not containing mediator dissolution slowing components and oxidizing agents which would have their expected functions in the methods of Tokunaga and Ye. No specific function is claimed to the lack of such components nor how the identification is performed.

The claims differ from the above references in that they specify ranges of time for the determination if the sample is a test or control sample, and storing identification information.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to determine whether the solution is a test or control in any selected time range in view of the above references. No criticality or novelty is seen in the claimed time ranges. Regarding storing or not storing identification information, no function or result is attributed to either choice and it would not appear to be novel to do either in view of the sample being identified as either test or control. The point of novelty resides in the identification, not what one does with the data after the data is identified.

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Claims 1-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 last line, it is not clear what the meaning of obtaining sample identification information may be. No nexus is seen between determining whether the sample is a test or control sample and obtaining identification information. In view of the above, the significance of claim 4 is not seen. In claim 7 "said test fluids" lacks definite antecedent basis. In claim 12 is unclear as to what sample may be intended. Claim 13 does not begin with a capitalized term. Please check claim 14 for typos.

The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

Moorman (5,356,782) teaches analytical test apparatus with positive and negative controls.

Neel (US 2003/0203498 A1) teaches glucose sensing apparatus.

Ryan (4,729,959) teaches glucose reference control solutions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Monday - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-1235. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Ralph Gitomer
Primary Examiner
Art Unit 1651

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200